

DADE

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DADE INTERNATIONAL

Chemistry Systems
P.O. Box 6101
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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Drug Calibrator II

Summary of Safety and Effectiveness

Drug Calibrator II is an *in vitro* diagnostic product intended for the calibration of test methods packaged in FLEX™ reagent cartridges.

Drug Calibrator II is a liquid bovine serum base product containing weighed-in quantities of purified drugs. It is packaged as 10 vials, two vials each of five levels. Each vial contains 5.0 mL.

Drug Calibrator II is substantially equivalent to the Dimension® Drug Calibrator as they are both intended to be used as calibrators for drug methods and are spiked with purified drugs.

Carolyn K. George

Carolyn K. George
Regulatory Affairs and
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Date